

STATE OF MICHIGAN  
DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES  
Before the Director of Insurance and Financial Services

In the matter of:

██████████,

Petitioner,

v

File No. 150913-001-SF

University of Michigan, Plan Sponsor,

and

Blue Cross Blue Shield of Michigan, Plan Administrator,

Respondents.

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Issued and entered  
this 16<sup>th</sup> day of December 2015  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

██████████ (Petitioner) was denied coverage for a breast digital tomosynthesis by her health plan.

On November 16, 2015, the Petitioner filed a request with the Director of Insurance and Financial Services for an external review of that denial under Public Act No. 495 of 2006 (Act 495), MCL 550.1951 *et seq.* On November 23, 2015, after a preliminary review of the information submitted, the Director accepted the request.

The Petitioner receives health care benefits through a group plan sponsored by the University of Michigan (the plan), a self-funded governmental health plan subject to Act 495. Blue Cross Blue Shield of Michigan (BCBSM) administers the plan. The Director immediately notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. The Director received BCBSM's response on November 24, 2015.

Section 2(2) of Act 495, MCL 550.1952(2), authorizes the Director to conduct this external review as though the Petitioner were a covered person under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The medical issues in this case were evaluated by an independent review organization which provided its analysis and recommendation to the Director on December 7, 2015.

## II. FACTUAL BACKGROUND

The Petitioner's health care benefits are described in BCBSM's *Community Blue Group Benefits Certificate ASC*<sup>1</sup> (the certificate).

On April 28, 2015, the Petitioner had a digital tomosynthesis of both breasts. Digital tomosynthesis, also called 3-D mammography, is used to detect breast cancer and creates a three-dimensional picture of the breasts using X-rays. BCBSM denied coverage for the service, saying it was experimental or investigational and therefore not a covered benefit.

The Petitioner appealed the denial through the plan's internal grievance process. At the conclusion of that process BCBSM issued a final adverse determination on October 1, 2015, affirming the denial. The Petitioner now seeks review of that final adverse determination from the Director.

## III. ISSUE

Was the Petitioner's digital tomosynthesis experimental or investigational for treatment of her condition?

## IV. ANALYSIS

### Petitioner's Argument

In her request for an external review, the Petitioner wrote:

I'm denied payment / coverage for digital breast tomosynthesis after procedure completed. I had same procedure in January 2012 procedure covered by insurance.

Because of my complexity of my mammograms it was strongly recommended regular molecular breast imaging be performed both by radiologist & gynecologist.

Now insurance denied payment stating it's experimental.

### BCBSM's Argument

In the final adverse determination, a BCBSM representative explained the denial:

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<sup>1</sup> BCBSM form no. 457F, effective 02/15.

. . . After review, I confirmed our denial of payments must be maintained because the service you received is considered Experimental / investigational.

The BCBSM/BCN Joint Uniform Medical Policy Committee (JUMP) has determined that the digital breast tomosynthesis service (procedure code 77063) is experimental / investigational. Experimental / investigational are not a benefit of your coverage. Therefore, payment is not available.

\* \* \*

A board-certified M.D. in Family Practice reviewed your claim, your appeal, and your health care plan benefits for Blue Cross Blue Shield of Michigan (BCBSM). The review determined:

We reviewed your appeal regarding the denial of coverage for your digital breast tomosynthesis (3D mammogram). Per the current Blue Cross Blue Shield of Michigan medical policy "Digital Breast Tomosynthesis," digital tomosynthesis is considered experimental / investigational. This is because there is insufficient evidence that the use of digital tomosynthesis improves health outcomes. Therefore, we cannot approve this request.

### Director's Review

The certificate has this exclusion (p. 127):

#### **Experimental Treatment**

##### Services That Are Not Payable

We do not pay for experimental treatment (including experimental drugs or devices) or services related to experimental treatment. . . .

“Experimental treatment” is defined (certificate, p. 142) as

[t]reatment that has not been scientifically proven to be as safe and effective for treatment of the patient's conditions as conventional treatment. Sometimes it is referred to as “investigational” or “experimental services.”

To evaluate the question of whether the digital breast tomosynthesis was experimental, the Director presented the issue to an independent review organization (IRO) for analysis as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO physician reviewer is board certified in radiology, has been in active practice for more than 15 years, and is familiar with the medical management of patients with the Petitioner's condition. The IRO report included this following analysis and recommendation:

The MAXIMUS physician consultant explained that breast tomosynthesis is becoming more and more routine. The Centers for Medicare and Medicaid Services now reimburse for digital breast tomosynthesis in addition to full field digital mammography for Medicare and MediCal patients.

The physician consultant indicated that the addition of digital breast tomosynthesis reduces false positives and increases cancer detection when compared to 2D full field digital mammography alone. The consultant also indicated that digital breast tomosynthesis reduces recall rates by 15 to 17% as 3D allows for separation of structures to differentiate architectural distortion from masses and overlapping fibroglandular tissue. The physician consultant further indicated that digital breast tomosynthesis increased cancer detection by 33 to 53%. Cancer detection rates increased from 6 cancers in 1,000 women screened with 2D to 8 cancers in 1,000 women screened with 3D. The physician consultant explained that 3D allows for better characterization of possible masses, speculation and architectural distortion. The consultant also explained that the use of digital breast tomosynthesis is therefore supported for routine screening mammography.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that the digital breast tomosynthesis service that the member underwent on 4/28/15 was not experimental / investigational for diagnosis and treatment of her condition. [Citations omitted]

The Director is not required to accept the IRO's recommendation. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). However, the recommendation is afforded deference by the Director. In a decision to uphold or reverse an adverse determination, the Director must cite "the principal reason or reasons why the [Director] did not follow the assigned independent review organization's recommendation." MCL 550.1911(16)(b). The IRO's analysis is based on extensive experience, expertise, and professional judgment. In addition, the IRO's recommendation is not contrary to any provision of the certificate. MCL 550.1911(15).

The Director, discerning no reason why the IRO's recommendation should be rejected in this case, finds that the Petitioner's April 28, 2015, digital breast tomosynthesis was not experimental and therefore is a covered benefit.

#### **V. ORDER**

The Director reverses the plan's October 1, 2015, final adverse determination.

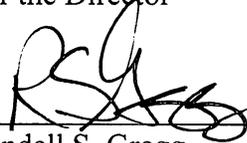
The plan shall immediately cover the Petitioner's April 28, 2015, screening digital breast tomosynthesis and related facility fees and shall, within seven days of providing coverage, furnish the Director with proof it has implemented this Order.

To enforce this Order, the Petitioner may report any complaint regarding its implementation to the Department of Insurance and Financial Services, Health Care Appeals Section, at this toll free number: (877) 999-6442.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this order may seek judicial review no later than 60 days from the date of this order in the circuit court for the county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Department of Insurance and Financial Services, Office of General Counsel, Post Office Box 30220, Lansing, MI 48909-7720.

Patrick M. McPharlin  
Director

For the Director

A handwritten signature in black ink, appearing to read 'R. S. Gregg', is written over a horizontal line.

Randall S. Gregg  
Special Deputy Director